**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| **In re Application of:** | Eric H. Kuhrts |
| **Serial No.:** | 10/008,778 |
| **Filing Date:** | November 13, 2001 |
| **Docket Number:** | 068911.0076 |
| **Title:** | NOVEL ANTI-INFLAMMATORY CYCLOOXYGENASE INHIBITORS |
| **Examiner:** | M. Meller |
| **Art Unit:** | 1654 |

**CERTIFICATE OF MAILING (37 C.F.R. § 1.8)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: December 19, 2005

Angelo J. Mignanelli

**MAIL STOP RCE**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

**TRANSMITTAL LETTER**

Enclosed herewith for filing in connection with the above-identified patent application are the following:

1) Request for Continued Examination (RCE) Transmittal;

2) Petition for a Two-Month Extension of Time;

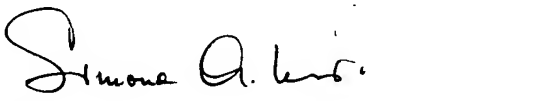
3) Copy of the entire submission dated August 18, 2005; and

4) Acknowledgment Postcard.

No additional costs are believed to be due in connection with the filing of this disclosure. However, please charge any necessary fees to our Deposit Account 50-1133.

Respectfully submitted,

McDermott, Will and Emery LLP



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Date: December 19, 2005

COPY OF AUGUST 18, 2005 SUBMISSION

# Auto-Reply Facsimile Transmission

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**FACSIMILE**

**Date:** August 18, 2005 **Time Sent:**

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| Examiner M. Meller | U.S. Patent Office (Group 1600) | 571.273.8300 | 571.272.0610 |

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**Re:** **IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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|---|---|---|
| **In re Application of:** | Kuhrts, Eric | Group Art Unit: 1634 |
| **Serial No.:** | 10/008,778 | Examiner: Meller, Michael V. |
| **Client-Matter No.:** | 068911.0076 | |
| **Filed:** | November 13, 2001 | |
| **For:** | Novel Anti-Inflammatory Cyclooxygenase Inhibitors | |

**Message: See Attached Documents: Amendment and Response to Final Office Action Pursuant to 37 C.F.R. § 1.116.**

MIA 299345-1.068911.0076



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U.S. practice conducted through McDermott Will & Emery LLP.
201 South Biscayne Boulevard 22nd Floor Miami, Florida 33131-4336 Telephone: 305.358.3500

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**Re:** **IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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|---|---|---|
| **In re Application of:** | Kuhrts, Eric ) | Group Art Unit: 1654 |
| **Serial No.:** | 10/008,778 ) | Examiner: Meller, Michael V. |
| **Client-Matter No.:** | 068911.0076 ) | |
| **Filed:** | November 13, 2001 ) | |
| **For:** | Novel Anti-Inflammatory ) | |
| | Cyclooxygenase Inhibitors ) | |

**Message: See Attached Documents: Amendment and Response to Final Office Action Pursuant to 37 C.F.R. § 1.116.**

MIA 299345-1.068911.0076



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**Date:** August 18, 2005 **Time Sent:**

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| Examiner M. Meller | U.S. Patent Office (Group 1600) | 571.273.8300 | 571.272.0610 |

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| | | *Number of Pages, Including Cover:* | 16 |

**Re:** **IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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|---|---|---|
| **In re Application of:** | Kuhrts, Eric | Group Art Unit: 1654 |
| **Serial No.:** | 10/008,778 | Examiner: Meller, Michael V. |
| **Client-Matter No.:** | 068911.0076 | |
| **Filed:** | November 13, 2001 | |
| **For:** | Novel Anti-Inflammatory Cyclooxygenase Inhibitors | |

**Message: See Attached Documents: Amendment and Response to Final Office Action Pursuant to 37 C.F.R. § 1.116.**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | | |
|---|---|---|---|
| In re Application of: | Kuhrts, Eric | Examiner: | M. Meller |
| Serial No: | 10/008,778 | Art Unit | 1654 |
| Filing Date: | November 13, 2001 | | |
| Title: | NOVEL ANTI-INFLAMMATORY CYCLOOXYGENASE INHIBITORS | | |
| Attorney Docket No. | 068911.0076 | | |

**CERTIFICATE OF FACSIMILE TRANSMISSION**

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Date: 8/18/05

Angelo J. Mignanelli

**MAIL STOP AF**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

**TRANSMITTAL LETTER**

Enclosed herewith for filing in connection with the above-identified patent application are the following:

1) Amendment and Response to Final Office Action Pursuant to 37 C.F.R. § 1.116;
2) Petition for a Three Month Extension of Time; and
3) Notice of Appeal.

Respectfully submitted,

Simona A. Levi-Minzi, Ph.D
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Date: August 18, 2005

Docket No.: 068911.0076



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|---|---|---|---|
| Applicant | : | Kuhrts, Eric | Customer No.: 41552 |
| Appl. No. | : | 10/008,778 | Confirmation No.: 4731 |
| Filed | : | November 13, 2001 | |
| Title | : | NOVEL ANTI-INFLAMMATORY CYCLOOXYGENASE INHIBITORS | |
| Grp./A.U. | : | 1654 | |
| Examiner: | : | Michael V. Meller | |

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Date: August 18, 2005

Angelo J. Mignanelli

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

## AMENDMENT AND RESPONSE TO FINAL OFFICE ACTION PURSUANT 37 C.F.R. § 1.116

This paper is responsive to the Office Action dated February 18, 2005 (the "Action"). Claim amendments are set forth at page 2. Remarks are set forth at page 6.

## AMENDMENT TO THE CLAIMS

*A listing of the claims presented in this patent application appears below. This listing replaces all prior versions and listings of the claims in this patent application.*

1. (Withdrawn) A pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity.

2. (Withdrawn) The Pharmaceutical composition of claim 1, wherein the COX-2 inhibitor comprises a botanical COX-2 inhibitor.

3. (Withdrawn) The pharmaceutical composition of claim 1, wherein the COX-2 inhibitor comprises iso-alpha acids.

4. (Withdrawn) The pharmaceutical composition of claim 3, wherein the iso-alpha acids are obtained from a supercritical carbon dioxide extraction of whole hops.

5. (Withdrawn) The therapeutic composition of claim 1, wherein the dose of the COX-2 inhibitor ranges from about 5 mg. to about 1,000 mg. per day.

6. (Withdrawn) The pharmaceutical composition of claim 3, wherein the dose of the iso-alpha acids is 100 mg. to about 1,000 mg. per day.

7. (Withdrawn) The pharmaceutical composition of claim 6 wherein the dose of iso-alpha acids is 200 mg. to 600 mg.

8. (Withdrawn) The pharmaceutical composition of claim 1, further comprising a mineral salt or alkali earth salt, or a mineral carbonate.

9. (Withdrawn) The pharmaceutical composition of claim 3, further comprising a mineral salt or alkali earth salt or mineral carbonate.

10. (Withdrawn) The pharmaceutical composition of claim 9, wherein the mineral salt or alkali earth salt is potassium hydroxide.

11. (Withdrawn) The pharmaceutical composition of claim 10, wherein the amount of potassium hydroxide per dose is 25 mg. to 500 mg.

12. (Withdrawn) A method for the treatment, of pain in mammals comprising: selecting the pharmaceutical composition of claim 1; and administering a therapeutically effective amount of the pharmaceutical composition to a mammal in need thereof.

13. (Currently amended) A method for treating osteoarthritis, rheumatoid arthritis or acute pain comprising: the step of administering a therapeutically effective amount of a pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity to a mammal having osteoarthritis, rheumatoid arthritis or acute pain.

14. (Withdrawn) The method of claim 12, wherein the COX-2 inhibitor comprises a botanical COX-2 inhibitor.

15. (Previously amended) The method of claim 13, wherein the COX-2 inhibitor comprises a botanical COX-2 inhibitor.

16. (Withdrawn) The method of claim 12, wherein the COX-2 inhibitor comprises iso-alpha acids.

17. (Previously amended) The method of claim 13, wherein the COX-2 inhibitor comprises iso-alpha acids.

18. (Withdrawn) The pharmaceutical composition of claim 1, wherein the ingredients are in sustained-release or immediate-release form, or a blend of sustained-release and immediate-release.

19. (Withdrawn) The pharmaceutical composition of claim 18, wherein the sustained-release form comprises: algal polysaccharides, chitosan, pectin, glucomannan, guar gum, xanthan gum, gum arabic, gum karaya, locust bean gum, keratin, laminaran, carrageenan, cellulose, modified cellulosic substances such as cellulose ether derivatives; methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, sodiumcarboxymethylcellulose, carboxymethylcellulose carboxypolymethylene, acrylic resin polymers, polyacrylic acid and homologues, polyethylene glycol, polyethylene oxide, polyhydroxylalkyl methacrylate, polyvinylpyrollidine, polyacrylamide, agar, zein, stearic acid, hydrogenated vegetable oils, carnauba wax, or gelatin.

20. (Withdrawn) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises an oral dosage forms that comprises tablets, hard shell capsules, soft gelatin capsules, beads, granules, aggregates, powders, gels, solids, semi-solids, or suspensions.

21. (Withdrawn) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises a topical dosage form that comprises lotions, transdermal delivery systems, including dermal patches, aerosols, nasal mists, suppositories, salves or ointments.

22. (Withdrawn) A method of producing an analgesic effect with reduced gastrointestinal and cardiovascular toxicity in a mammal comprising administering to said mammal a therapeutically effective analgesic amount of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33.

23. (Withdrawn) The method of claim 22, wherein the COX-2 inhibitor is from a botanical source.

24. (Withdrawn) The method of claim 23, wherein the COX-2 inhibitor is iso-alpha acids.

25. (Withdrawn) The method of claim 24, further comprising a mineral salt or alkali earth salt or mineral carbonate.

26. (Withdrawn) The method of claim 25, wherein the mineral salt is potassium hydroxide.

27. (Withdrawn) A method for producing a fast onset of pain relief in a mammal comprising administering to a mammal a therapeutically effective analgesic amount of iso-alpha acids.

## REMARKS

Reexamination and reconsideration in light of the foregoing amendments and following remarks is respectfully requested.

### I. AMENDMENTS

Claims 1 through 27 are pending. Claims 1 through 12, 14, 16 and 18 - 27 have been withdrawn from further consideration since they have been found to read on non-elected inventions. The finality of the requirement is acknowledged.

Claim 13 has been amended to further recite that the administration of the compositions contemplated is to a mammal having osteoarthritis, rheumatoid arthritis or acute pain. Support for the amendments may be found throughout the specification (see e.g., paragraph [0048] of the published application. Accordingly, these amendments and new claims do not raise an issue of new matter and entry thereof is respectfully requested.

Claims 13, 15 and 17 are pending. Claims 13, 15 and 17 have been rejected.

### II. CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 13, 15 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by JP 363211219 ("JP"). At page 3 of the Action, the Examiner has maintained the argument that "*JP teaches that a composition to prevent dental caries is made which reads on the invention.*" Essentially, the Examiner has maintained the rejections insofar as "*the claims do not require a patient to suffer from the claimed diseases/disorders*" (see Action at page 3). Applicant has amended Claim 13 (and thus, Claims 15 and 17 depending from

Claim 13) to be limited to the administration of the compositions of the invention to a mammal having osteoarthritis, rheumatoid arthritis or acute pain.

As previously maintained, JP does not teach methods for the treatment of osteoarthritis, rheumatoid arthritis or acute pain. The invention of Claims 13, 15 and 17 as amended is specifically directed to the treatment of mammals having osteoarthritis, rheumatoid arthritis or acute pain. Because JP relates exclusively to the *"preventing the proliferation of cariogenic bacteria"* (see JP, paragraph labeled PURPOSE) JP does not anticipate the methods of Claims 13, 15, and 17.

Accordingly, Applicant respectfully request reconsideration and withdrawal of the rejections in light of the amendments and remarks found herein.

## III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Claims 13, 15 and 17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over FR 002590589 ("FR"), GB 2072657 ("GB"), Forster *et al.* U.S. Patent No. 4.640,841 ("Forster"), Ting *et al.* U.S. Patent No. 6,020,019 ("Ting"), taken with JP.

At page 3 of the Action it is stated that *"FR, GB Forster and Ting all teach the claimed compound"*. And further, that *"JP teaches to administer it to prevent dental caries. Thus, it would have been prima facie obvious to administered <sic> the claimed composition."*

Arguably, FR, GB, Forster and Ting relate to iso-alpha acids and to preparation methods of the same without more. Note that none of these references is concerned with bioavailability of pharmaceutical compositions of iso-alpha acids. In addition. none of these references is concerned with pharmaceutical compositions having the property recited in the claims of the invention (*i.e.*, comprising a therapeutic quantity of

a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity).

JP is adduced to provide the teaching or suggestion to use iso-alpha acids therapeutically. Applicant aver that in light of the amendments herein, the obviousness rejections should be reconsidered and withdrawn.

Specifically, FR purports to teach a method to process alpha and beta acids by photochemically irradiation of the same under pressure. FR is merely a process patent which has no relevance to therapeutic modalities. Furthermore, FR relates exclusively to beer manufacturing. Accordingly, FR is not concerned with the treatment of any of the conditions addressed by the instant invention, bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity.

The GB reference relates to **beta** acids. Specifically, this reference purports to teach beer manufacturing methods suitable to obtain hulupones. In a variation of the beer making processes contemplated, patentee advocates mixing such hulupones with isohumulones to provide a beer soluble product which, as a bitter constituent, has all the taste properties of natural hops. Accordingly, GB is not concerned with the treatment of any of the conditions addressed by the instant invention, bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity.

Forster relates to hops extraction with supercritical carbon dioxide at pressures of about 100 to about 300 bar and temperatures above 100°C to yield a resin extract of first grade quality similar in its composition to an extract obtained with methylene chloride. The process is said to provide additional hop substances at higher total yield which increase the potential bitterness of the beer. Accordingly, Forster is not concerned with

the treatment of any of the conditions addressed by the instant invention, bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity.

Ting relates to the use of $CO_2$ as a reaction solvent in the hydrogenation of organic compounds. The method is said to be useful for making tetrahydroiso-alpha-acids from alpha-acids, iso-alpha-acids, or beta-acids. While this patent does relate to certain iso-alpha acids, this patent is not concerned with the treatment of the indications addressed by the instant application. Similarly, Ting is not concerned with the bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity.

JP relates exclusively to the *"preventing the proliferation of cariogenic bacteria"* (see JP, paragraph labeled PURPOSE). Accordingly, JP is not concerned with the treatment of any of the conditions addressed by the instant invention, bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity. JP thus, does not cure the deficiencies of either one of the primary references cited.

Coupled to the absence of any teaching or suggestion, there is no motivation to modify the art cited to arrive at the invention of amended claims 13, 15 and 17. Similarly, one of skill in the art –without the benefit of the teaching of Applicant's disclosure – would not have had a reasonable expectation of success in treating osteoarthritis, rheumatoid arthritis or acute pain using the selected pharmaceutical compositions of the invention. Simply stated, patents related to make testier beer in combination with a patent related to prevent dental caries cannot possibly lead one of

skill to arrive to a pharmaceutical preparation for therapeutic uses according to the instant invention absent more.

For the foregoing reasons, applicants aver that a *prima facie* case of obviousness of the claimed invention has not been established.

Accordingly, it is respectfully requested that the rejections of Claims 13, 15 and 17 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

**<<CONCLUSION SECTION ON THE NEXT PAGE>>**

COPY

## III. CONCLUSION

On the basis of the foregoing remarks and amendments, Applicants respectfully submit that amended claims 13, 15 and 17 are in condition for allowance. Passage to issue is respectfully requested.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below.

A Request for a Three (3) Month Extension of Time, up to and including August 18, 2005 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under paragraph 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectfully submitted,
McDERMOTT WILL & EMERY LLP

Simona A. Levi-Minzi, Ph.D.
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Date: August 18, 2005

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| Attorney Docket No. | 068911.0076 | | |

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Date: 8/18/05

Angelo J. Mignarelli

**PETITION FOR EXTENSION OF TIME**

**MAIL STOP AF**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

It is respectfully requested that the time for response to the Final Office Action dated February 18, 2005, now due to expire August 18, 2005, be extended for three (3) months.

Please charge our Deposit Account No. 50-1133 the amount of $1050 for the three (3) month extension of time pursuant to 37 C.F.R. § 1.136(a)(5). The fee charged reflects the applicant's claims to small entity status pursuant to 37 C.F.R. § 1.27.

Respectfully submitted,

Simona A. Levi-Minzi, Ph.D
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Date: August 18, 2005